

HOLLAND & KNIGHT LLP

One Atlantic Center
1201 West Peachtree Street N.E.
Suite 2000
Atlanta, Georgia 30309-3400

404-817-8500
404-861-0470 Fax
www.hkllaw.com

Annapolis
Atlanta
Beltsville
Boston
Boulder
Chicago
Fort Lauderdale
Jacksonville
Lakeland
Los Angeles
Miami
New York
Northern Virginia
Orlando
Portland
Providence
St. Petersburg
San Antonio

Salt Lake City
Seattle
Tallahassee
Tampa
Washington, D.C.
West Palm Beach

International Offices:
Caracas**
Helsinki
Mexico City
Rio de Janeiro
Sao Paulo
Tel Aviv**
Tokyo

*Holland & Knight LLC
**Representative Office

FACSIMILE

TO:		
Commissioner for Patents	U.S. Patent and Trademark Office	703-872-9302
NAME	COMPANY/FIRM	FAX NUMBER
Alexandria	VA	703-872-9301
CITY	STATE	(TELEPHONE NUMBER)
FROM:		
Patrea L. Pabst	404-817-8473	12
NAME	TELEPHONE	TOTAL PAGES (Including Cover Sheet)
FOR THE RECORD:		
DATE: September 25, 2003	URGENCY: <input type="checkbox"/> SUPER RUSH	<input checked="" type="checkbox"/> RUSH <input type="checkbox"/> REGULAR
FAKED BY: Pam Turnbough	FILE #:	CLIENT NAME:
CONFIRMED: <input type="checkbox"/> YES <input type="checkbox"/> NO	NAME:	TIME:
<p>If you did not receive all of the pages or find that they are illegible, please call (404) 817-8500</p> <p>CONFIDENTIALITY NOTICE: This facsimile, along with any documents, files, or attachments, may contain information that is confidential, privileged, or otherwise exempt from disclosure. If you are not the intended recipient or a person responsible for delivering it to the intended recipient, you are hereby notified that any disclosure, copying, printing, distribution or use of any information contained in or attached to this facsimile is strictly prohibited. If you have received this facsimile in error, please immediately notify us by facsimile or by telephone collect at the numbers stated above, and destroy the original facsimile and its attachments without reading, printing, or saving in any manner. Your cooperation is appreciated. Thank you.</p>		

MESSAGE:**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Peter J. Houzago, Peter N. Morgan, Peter H. Hirst, Duncan J. Westland, and Ian R. Wilding

Serial No.: 10/607,721 **Group Art Unit:** 3763

Filed: June 27, 2003 **Examiner:** Not yet assigned

For: INGESTIBLE DEVICE

ATL1 #587673 v1

PTO/SB/21 (09-03)
Approved for use through 07/01/2005. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/607,721	
	Filing Date	June 27, 2003	
	First Named Inventor	Peter J. Houzago	
	Art Unit	3763	
	Examiner Name	Not yet assigned	
Total Number of Pages in This Submission	//	Attorney Docket Number	PHAG 100 DIV

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input checked="" type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input checked="" type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) <input type="text"/> Remarks	<input type="checkbox"/> After Allowance communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> RECEIVED CENTRAL FAX CENTER SEP 26 2003 </div> <div style="font-size: 2em; opacity: 0.5;">OFFICIAL</div> </div>		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual name	Patricia L. Papst, Esq., Reg. No. 31,284 Holland & Knight LLP	
Signature	Suite 2000, One Atlantic Center, 1201 West Peachtree Street, N.E., Atlanta, GA 30309-3400	
Date	September 24, 2003	

CERTIFICATE OF TRANSMISSION/MAILING	
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.	
Typed or printed name	Pam Turnbough
Signature	<i>Pam Turnbough</i>
Date	September 25, 2003

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 38 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

078230/00035

PTO/S5/17 (08-03)

Approved for use through 07/31/2006, CMB 0851-0032

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL

for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 130.00

Complete if Known

Application Number	10/607,721
Filing Date	June 27, 2003
First Named Inventor	Peter J. Houzago
Examiner Name	Not yet assigned
Art Unit	3763
Attorney Docket No.	PHAG 100 DIV

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:

Deposit Account Number	50-1666
Deposit Account Name	Holland & Knight LLP

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☐ Charge any additional fee(s) during the pendency of this application☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity	Small Entity	Fee Code	Fee Description	Fee Paid
1001	750	2001	Utility filing fee	
1002	330	2002	Design filing fee	
1003	520	2003	Plant filing fee	
1004	750	2004	Relapse filing fee	
1005	160	2005	Provisional filing fee	

SUBTOTAL (1) (\$) .00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
19	-20** =	X	
1	-3** =	X	
Multiple Dependent			

Large Entity	Small Entity	Fee Code	Fee Description	Fee Paid
1202	16	2202	Claims in excess of 20	
1201	64	2201	Independent claims in excess of 3	
1203	280	2203	Multiple dependent claim, if not paid	
1204	64	2204	** Relapse independent claims over original patent	
1205	16	2205	** Relapse claims in excess of 20 and over original patent	

SUBTOTAL (2) (\$) .00

**or number previously paid, if greater. For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Code	Fee Description	Fee Paid
1051	130	2051	05 Surcharge - late filing fee or oath	
1052	50	2052	25 Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130 Non-English specification	
1812	2,520	1812	2,520 For filing a request for ex parte reexamination	
1804	620*	1804	620* Requesting publication of SIR prior to Examiner action	
1805	1,040*	1805	1,040* Requesting publication of SIR after Examiner action	
1251	110	2231	55 Extension for reply within first month	
1252	410	2252	205 Extension for reply within second month	
1253	930	2253	465 Extension for reply within third month	
1254	1,450	2254	725 Extension for reply within fourth month	
1255	1,970	2255	965 Extension for reply within fifth month	
1401	320	2401	180 Notice of Appeal	
1402	320	2402	190 Filing a brief in support of an appeal	
1403	280	2403	140 Request for oral hearing	
1451	1,510	1451	1,510 Petition to institute a public use proceeding	
1452	110	2452	55 Petition to revive - unavoidable	
1453	1,300	2453	650 Petition to revive - unintentional	
1501	1,300	2501	650 Utility issue fee (or reissue)	
1502	470	2502	235 Design issue fee	
1503	650	2503	315 Plant issue fee	
1460	150	1460	150 Petitions to the Commissioner	150.00
1607	50	1607	50 Processing fee under 37 CFR 1.17(d)	
1606	180	1606	180 Submission of Information Disclosure Stmt	
0021	40	0021	40 Recording each patent assignment per property (times number of properties)	
1809	750	2809	375 Filing a submission after final rejection (37 CFR 1.129(a))	
1910	750	2910	375 For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375 Request for Continued Examination (RCE)	
1802	900	1802	900 Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 130.00

SUBMITTED BY

Name (Print/Type)	Patricia L. Pabst	Registration No.	31,284	Telephone (404) 817-6473
Signature		Examination Agent		Date
				September 24, 2003

WARNING: Information on this form may become public. Credit card information should not

be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22315-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22315-1450.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Peter J. Houzego, Peter N. Morgan, Peter H. Hirst, Duncan J. Westland, and Ian R. Wilding

Serial No.: 10/607,721

Group Art Unit: 3763

Filed: June 27, 2003

Examiner: Not yet assigned

For: *INGESTIBLE DEVICE*

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO NOTICE OF OMITTED ITEM(S)
IN A NONPROVISIONAL APPLICATION**

Sir:

Responsive to the Notice of Omitted Item(s) in a Nonprovisional Application, mailed September 22, 2003, applicants enclose the following for filing in the above-identified application:

1. Pages 19, 20, 34 and 35 of the Specification;
2. Transmittal Form PTO/SB/21;
3. Fee Transmittal (in duplicate); and
4. Authorization to charge Deposit Order Account No. 50-1868 in the amount of \$130.00 for filing a Petition under 37 CFR 1.182 for large entity.

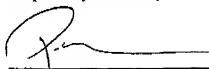
U.S.S.N.: 10/607,721
Filed: June 27, 2003
Response to Notice of Omitted Item(s)
in a Nonprovisional Application

Applicants also enclose a copy of the Notice of Omitted Item(s) in a Nonprovisional Application, mailed September 22, 2003. The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment in connection with this matter, to Deposit Account No. 50-1868.

The undersigned hereby certifies that the enclosed pages of the specification are true and accurate copies of the specification as originally filed in the parent application, U.S.S.N. 09/742,936, which claims priority to United Kingdom patent application No. 9930000.6 filed December 21, 1999.

Issuance of a filing receipt and forwarding of the file to the examiner is earnestly solicited.

Respectfully submitted,



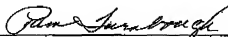
Patrea L. Pabst
Reg. No. 31,284

Date: September 25, 2003
HOLLAND & KNIGHT LLP
Suite 2000, One Atlantic Center
1201 West Peachtree Street, N.E.
Atlanta, Georgia 30309-3400
(404) 817-8473 (Telephone)
(404) 817-8588 (Fax)

U.S.S.N: 10/607,721
Filed: June 27, 2003
Response to Notice of Omitted Item(s)
In a Nonprovisional Application

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this RESPONSE TO NOTICE OF OMITTED ITEM(S) IN A
NONPROVISIONAL APPLICATION, and any paper referred to as being attached or
enclosed, are being facsimile transmitted on the date shown below to Commissioner for Patents,
Alexandria, VA 22313-1450.



Pam Turnbough

Date: September 25, 2003

1219623_v1

RECEIVED
CENTRAL FAX CENTER

SEP 26 2003

OFFICIAL

PHAG 100 DIV
078230/00035

mechanism; (b) a switch for switchably operating the transmitter; and (c) a switch member operatively interconnecting the actuator mechanism and the switch such that operation of the actuator mechanism causes the switch member to operate the said switch..

- 5 Preferred features of the sixth, seventh and eighth aspects of the invention are defined in the claims depending from Claims 39, 42, 50 and 69.

One preferred embodiment of the device includes a coil spring which operates to move a piston to expel the drug from inside the capsule through an opening at the other end of the capsule. An example of the dimensions and components that could be used would be for a volume of 1ml available to
10 contain the drug in the form of a cylinder 9mm in diameter and 16mm long. A coil spring of 8mm outer diameter compressed to a length of 4.6mm could exert an initial force of over 1kg and have a residual force of 0.2kg after it has travelled the 16mm.

15

Brief Description of the Figures

There now follows a description of preferred embodiments of the invention, by way of non-limiting example, with reference being made to the accompanying drawings in which:

- 20 Figure 1 is a perspective, partly sectioned view of an ingestible device according to the invention;

Figures 2a and 2b are, respectively, block diagram and schematic views of a receiver-transmitter circuit forming part of the Figure 1 device;

- 25 Figure 3 shows one embodiment of antenna for use in the Figure 1 device, including an antenna wire coiled about the capsule wall;

Figure 4 shows an alternative antenna, including an antenna wire coiled about a ferrite core within the device;

Figures 5a and 5b are, respectively, side elevational and plan views of an apparatus, according to the invention, for generating an oscillating, axial

Pf/AG 100
11211/1

magnetic field;

Figure 6 shows, schematically, a preferred embodiment of oscillating field generator;

- Figure 7 shows a further embodiment of oscillating field generator
5 according to the invention;

Figures 8a and 8b are, respectively plan and cross-sectional views of a restraint and switch combination, according to the invention, before actuation of the switch;

- Figures 9a and 9b are views, corresponding to the Figure 8 views, after
10 actuation of the switch;

Figures 10 to 12 show three kinds of energy source in the form of compression springs;

Figure 13 shows a restraining ring for retaining moveable components of the device of the invention within its housing, after dispensing of a substance;

- Figures 14a and 14b show further springs suitable for use as the energy
15 source;

Figure 15 is a plot comparing the force applied by springs, such as those shown in Figures 14a and 14b, against a force resisting opening of the reservoir of a capsule according to the invention;

- Figure 16 is a cross sectional view of one form of piston suitable for use
20 in the capsule of the invention;

Figure 17 is a similar view of another form of piston;

- Figures 18 and 19 show stages in the assembly of part of a device according to the invention, including a piston such as that shown in Figures 16
25 or 17; and a lost motion arrangement for breaking the breakable link on the pcb forming part of the device;

Figures 18 and 19 show steps in the assembly of the device; and

Figures 20 and 21 show two faces of a printed circuit board, forming part of the device, in plan view.

PHAD 100
1132/1

high energy storage characteristic suitable for use in the capsule 10.

5 Each spring 50a, 50b is coated with an insulator over at least part of and preferably all its length, to insulate the springs from one another in use and thereby reduce the chance of the springs creating an electrical or magnetic closed ring ("shorted turn") capable of coupling some of the energy of the electromagnetic field intended for coupling by the receiver 59.

10 Food grade PTFE ("Teflon"TM) is the preferred coating since it is biocompatible and absorbs little of the spring energy.

15 The terminus 50c at each end of each wire defining a said spring 50a, 50b is truncated to ensure that the terminal coils of the springs also do not form any closed rings that would undesirably couple energy from the energized field. In addition each terminal portion 50c is ground or otherwise formed flat (ie. flush with the next adjacent coil) so that in use of the springs 50a, 50b within capsule 10 they push the piston 16 evenly and without buckling.

20 The springs 50a, 50b are compressible such that the compressed length of each spring is about $\frac{1}{2}$ the length of its uncompressed state, that in the preferred embodiment is about 32mm. These dimensions allow for a sufficiently high spring force to act over the entire length of movement of piston 16.

25 Figure 15 is a plot of the spring force applied by a composite spring such as shown in Figure 11 or Figures 14a and b, against its extension. Figure 15 also plots the resistive force offered by a bung such as bung 14

including a rolling O-ring seal. As is evident from Figure 15, although the spring force declines during extension of the spring, during travel of the piston the spring force always exceeds the prevailing resistive force, even when the latter rises to a maximum on opening of the reservoir 12 as noted in Figure 15.

3. Wavy Springs as shown in Figures 12a and 12b

Thin washers 55 plastically deformed in circumferential waves act as compression springs. Multiple washers 55 welded peak to peak as shown can give the required extension.

Performance can be superior to a coil spring in this application as more of the available space can be utilised. Thus, for example, a 0.25mm thick annular washer with o.d. 8.5mm and i.d. 4.5mm could be formed to have 3 circumferential waves with a peak to peak height of 2mm. Welding 16 of these together at their peaks in the manner shown forms a wavy spring with a compressed length of 4mm, an extended length of 32mm and a force profile superior to a coil spring in the available space.

Figure 12a shows such a spring in the uncompressed state; and Figure 12b shows the spring when it is compressed, prior to expulsion of the substance 12a from the reservoir 12.

Figures 16 and 17 show embodiments of the piston 16 used to expel the contents of reservoir 12 of capsule 10.

The piston 16 of Figure 16 is intended for use when the reservoir 12 is charged with a substance in liquid form.

sentences caused by any omitted page(s), and/or amendment of the specification to cancel all references to any omitted drawing(s), relabel the drawing figures to be numbered consecutively (if necessary), and correct the references in the specification to the drawing figures to correspond with any relabeled drawing figures, is required. A copy of the drawing figures showing the proposed changes in red ink should accompany with any drawing changes. Such amendment and/or correction to the drawing figures, if necessary, should be by way of preliminary amendment submitted prior to the first Office action to avoid delays in the prosecution of the application.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

S.B.
Customer Service Center
Initial Patent Examination Division (703) 308-1202
PART 1 - ATTORNEY/APPLICANT COPY

RECEIVED
CENTRAL FAX CENTER

SEP 26 2003

OFFICIAL